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REMARKS

Favorable reconsideration is respectfully requested in view of the following remarks. Claims 1, 4-12 and 14-26 are pending.

Claims 1, 4-12 and 14-26 are rejected under 35 USC 112, second paragraph as being indefinite. Claim 1 recites pouring the liquid sample into the centrifugation tube so that substantially all of the liquid phase part of the liquid sample is absorbed by the water-absorbing particles, the water-absorbing particles being included within the centrifugation tube. Claim 1 further recites that the collecting solution is poured into the centrifugation tube without separating "the liquid phase part absorbed by the water absorbing resin particles" from the water absorbing resin particles that have absorbed the liquid phase part of the liquid sample. Thus, it is clear from the recited features that at the time the collecting solution is poured, the centrifugation tube includes the liquid phase part absorbed by the water-absorbing particles and the microorganism or cell caught on the surface of the water-absorbing resin particles. Thus, Applicants submit that claim 1 is fully consistent and definite. Withdrawal of the rejection is respectfully requested.

Claims 1, 4-8, 10-12, 14 and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sato (US Publication No. 2001/0009759) in view of Wardlaw (US Publication No. 2001/0033808) in view of Lyman (US Patent No. 4683058) and Tsuchiya (US Patent No. 5747277). Applicants respectfully traverse the rejection.

The rejection contends that Wardlaw cures what is missing in Sato. Applicants respectfully submit that the rejection is relying on the improper use of hindsight in the interpretation of the references.

Sato is directed to a method involving the use of a particular type of particles for the specific purposes of extracting viruses for nucleic amplification (paragraph [0004]). The reference notes that the prior art teaches soluble polymeric substances having cationic groups to separate viruses by sedimentation, and indicates that because the viruses are purified after sedimentation, the large quantity of protein mixed together with the viruses and the reagents to be mixed can inhibit the amplification of the viral gene (paragraph [0006]). To address such issues, the reference teaches the use of insoluble particles that bind specifically to viruses for the purposes of examining and diagnosing the viruses using nucleic-acid amplification (paragraph [0007]). The reference teaches that their insoluble particles have at least one of a cationic and an anionic group present on their surfaces (paragraph [0020]). The reference further teaches that the cationic or the anionic group must be present in certain amounts; otherwise the particles may not possess virus-separating ability (paragraphs [0023] and [0065]). The reference teaches that where the particles are hydrogel particles, the particles include a sulfonic acid monomer and a water-soluble crosslinkable monomer (paragraph [0074]). The reference further teaches that such hydrogel particles are formed by vigorously mixing a solution of the two monomers and an initiator with a non-polar solvent to which a surface-active agent has been added to form a water-in-oil type reverse micelle (Id.). The reference also teaches that the virus-binding particles are added to a sample in the form of a virus-separating reagent prepared by the virus-binding particles in a medium such as saline (paragraph [0097]). The reference also teaches that a polyvalent metal may be further added to bind the virus-binding particles at a higher proportion in some cases (paragraph [0085]). The reference teaches that after the virus-separating reagent is added to the sample, the virus-binding particles having only the viruses attached to the surfaces

are removed from the liquid, and the viruses are then separated from the virus-binding particles using a salt solution (paragraphs [0098-0099]).

It can be clearly understood from the above discussion that Sato teaches the use of a particular type of particles for separating only the viruses for the purposes of separating them from components that may adversely affect the amplification of the viral gene, that the particles are dispersed in solution before being added to the sample, and that the binding of the viruses to the particles is due to the presence of the cationic or anionic groups that are provided on the surfaces of the particles.

Wardlaw is directed to separating various formed constituents such as bacteria and cells, from a liquid constituent in a biological fluid sample (paragraphs [0001] and [0012]). The reference notes that the prior art teaches the separation of the formed constituents by the use of centrifugation and filtration, and that such methods can destroy the sample components or require prior knowledge as to the size of the target formed constituents (paragraphs [0006-0007]). In order to address such issues, the reference teaches a technique that operates in a quiescent manner and does not require the use of centrifugation or filters (paragraph [0009]). In particular, the reference teaches a chamber that includes a planar expandable wall that is disposed opposite a sample viewing portion (paragraph [0011]). The reference teaches that the planar expandable wall is a hydrogel layer that is planar, mirroring the planar bottom wall of the chamber (paragraph [0026]). When the sample is added, the hydrogel layer absorbs water from the sample and fills the chamber (paragraph [0012]). As the hydrogel layer expands, the formed constituents are captured on the moving planar surface of the hydrogel layer (Id.).

It can be clearly understood from the above discussion that Wardlaw teaches the use of a hydrogel layer, as opposed to particles, and that Wardlaw teaches separating formed constituents in general, as opposed to separating a specific component.

The rejection contends that Sato teaches a method of bringing a liquid sample into contact with the particles that in one embodiment are hydrogel particles which absorb water, that Wardlaw teaches absorbing resin particles that absorb substantially all of the liquid phase of the sample, that using hydrogel particles capable of absorbing essentially all of the liquid in the sample would aid in the separation and purification of the virus from the sample, and that it would have obvious to have modified Sato by using enough hydrogel particles to absorb essentially all of the liquid in the sample as suggested by Wardlaw.

However, as is clear from the discussion above, Sato is directed to achieving a result that is the exact opposite to that of Wardlaw. That is, Sato is directed to separating only the viruses, whereas Wardlaw is directed to separating formed constituents in general. Sato in fact specifically is intended to utilize particular types of particles that isolate viruses from other components in a sample which may adversely affect amplification. As such, the use of hydrogel particles in amounts that would absorb essentially all of the liquid in the sample as taught by Wardlaw would in fact frustrate the purposes of Sato, as such use of the hydrogel particles would capture unwanted components that may adversely affect the amplification reaction of the viral gene, which is often very sensitive to the presence of other components as indicated by Sato.

Moreover, Sato teaches adding the virus-binding particles to a sample in the form of a virus-separating reagent, which is prepared by dispersing the virus-binding particles in an aqueous medium. Nothing in Sato teaches that the particles are added in amounts that substantially absorb all of the liquid of the sample. In fact, Sato is silent as to whether their

hydrogel particles are even capable of absorbing water. Even if it is assumed that Sato's hydrogel particles are capable of absorbing water, it is clear that more of the hydrogel particles would need to be added in order to absorb essentially all of the liquid of the sample in addition to the liquid from the virus-separating reagent. The reference clearly notes that the addition of virus-binding particles in too large a quantity is undesirable (paragraph [0097]). As such, it is far from clear whether the viruses would even separate if Sato's hydrogel particles were added in amounts that absorb essentially all of the liquid of the sample as indicated by the rejection.

Accordingly, contrary to the rejection's position, Applicants submit that it would not have been obvious to combine Sato and Wardlaw.

The rejection further contends that it would have been obvious to have modified the method of Sato and Wardlaw by performing the step of binding the virus to the particles on a filter in a centrifuge and then centrifuging the tube so that the virus accumulates at the bottom of the centrifugation tube as suggested by Lyman and Tsuchiya. However, as indicated above, Sato specifically teaches that their particles capture only the viruses, and teaches away from using the particles in a manner that would capture components other than viruses as taught by Wardlaw. As such, the combination of Sato and Wardlaw would frustrate the purposes of Sato. In addition, as noted above, Wardlaw teaches that their chamber captures formed constituents in general in a quiescent manner, and teaches away from the use of centrifugation and filters as taught by Lyman and Tsuchiya. Thus, Applicants respectfully submit that it would not have been obvious to combine the references as indicated by the rejection.

Accordingly, claim 1 and the dependent claims therefrom are patentable over the references taken alone or together.

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Claims 9 and 16-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sato in view of Lyman and Tsuchiya as applied to claims 1, 8 and 14 above and in further view of US Patent No. 5,726,021 (Britschgi et al.). Applicants respectfully traverse the rejection.

Claim 1 has been distinguished above. Britschgi does not remedy the deficiencies of Sato, Lyman and Tsuchiya. Claims 9 and 16-24 depend from claim 1 and are patentable over the references for at least the same reasons discussed above. Applicants do not concede the correctness of the rejection.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sato in view of Lyman and Tsuchiya as applied to claim 14 and further in view of US Patent No. 5,658,779 (Krupey). Applicants respectfully traverse the rejection.

Claim 1 has been distinguished above. Krupey does not remedy the deficiencies of Sato, Lyman and Tsuchiya. Claim 15 depends from claim 1 and is patentable over the references for at least the same reasons discussed above. Applicants do not concede the correctness of the rejection.

In view of the above, favorable reconsideration in the form of a notice of allowance is requested. Any questions or concerns regarding this communication can be directed to the attorney-of-record, Douglas P. Mueller, Reg. No. 30,300, at (612) 455.3804.

Respectfully submitted,

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